OCT 18 2006

**Torbot Group, Inc., Jobskin Division**
**510(k) Summary**

## I. General Information on Submitter

Name: Torbot Group, Inc., Jobskin Division

Address: 653 Miami Street
Toledo, OH 43605

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Name of Contact Person: Greg Johnson

Date Summary Prepared: May 16, 2006

## II. General Information on Device

Trade name: Torbot Vascular Compression Garments

Classification Name: Medical Support Stocking

## III. Predicate Devices

Torbot Vascular Compression Garments are substantially equivalent to the following devices:

- Jobst Custom Compression Garments K925154
- Jobst Elvarex Compression Garments K963573
- Jobst Ready-To-Wear Arm Sleeves K991570
- D.R. Medical Controlled Pressure Garments K001300
- Dr. Emily Iker's DM Sleeve K021102
- Jobst Ready-To-Wear Gauntlet K013852

## IV. Description of the Device

Torbot Vascular Compression Garments, custom and ready-to-wear, help to prevent pooling of blood and fluid in the extremities by applying controlled graduated pressure. The fabric used is comprised of nylon and spandex which is used in the predicate devices.

## V. Intended Use

Torbot Vascular Compression Garments are intended to be used to apply pressure to the extremity and are indicated for use in the management of pooling of blood and/or lymphedema.

## VI. Technological Characteristics of Device Compared to Predicate Device

Compression for the Torbot Vascular Garments, as well as all the predicate devices, is provided by elastic yarns that act circumferentially on the extremity. The gradient compression present in these products helps reduce capillary leakage and improve capillary and lymphatic drainage and/or absorption. Consequently, they can be used to manage the same indications, i.e. edema and lymphedema.

Greg Johnson
General Manager
Torbot Group, Inc., Jobskin Division

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Torbot Group, Incorporated
Mr. Greg Johnson
General Manager
Jobskin Division
653 Miami Street
Toledo, Ohio 43605

OCT 18 2006

Re: K061411
Trade/Device Name: Torbot Vascular Compression Garment
Regulation Number: 880.5780
Regulation Name: Medical Support Stocking
Regulatory Class: II
Product Code: DWL
Dated: August 14, 2006
Received: August 14, 2006

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061411

# Indications for Use

510(k) Number (if known):_____

Device Name: Torbot Vascular Compression Garment

Indications For Use: Torbot Vascular Compression Garments are intended to be used to apply pressure to the extremity and are indicated for use in the management of pooling of blood and/or lymphedema.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for AOW 10/17/2002

(Sign Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...mber: K061411